

Annexure A

[TO BE PUBLISHED IN THE GAZETTE OF INDIA, PART III, SECTION 4]

Ministry of Health and Family Welfare
(Food Safety and Standards Authority of India)

Notification

New Delhi, the....., 2017

F.No. TPA/01/REG/FSSAI-2017.- The following draft of the Food Safety and Standards (Food Safety Auditing) Regulations, 2017, which the Food Safety and Standards Authority of India proposes to make with the previous approval of the Central Government, in exercise of powers conferred by clause (c) of sub-section (2) of section 16 read with section 44 of the Food Safety and Standards Act, 2006 (34 of 2006), is hereby published as required under sub-section (1) of section 92 of the said Act, for the information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulations shall be taken into consideration after the expiry of a period of thirty days from the date on which the copies of the Gazette in which the notification is published are made available to the public;

Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi – 110002 or sent to the e-mail address of the Food Authority at regulation@fssai.gov.in;

Objections or suggestions which may be received from any person with respect to the said draft regulations before the expiry of the period specified above, shall be considered by the Food Safety and Standards Authority of India.

Draft Regulations

Part-I GENERAL

1. These regulations may be called the Food Safety and Standards (Food Safety Auditing) Regulations, 2017.
2. Definitions. - (1) In these regulations, unless the context otherwise requires,-
 - (a) “Act” means the Food Safety and Standards Act, 2006 (34 of 2006);
 - (b) “accreditation” means a third party attestation of the competence of the auditing agencies to carry out specific food safety auditing;
 - (c) “accreditation body” means an authority that performs accreditation and shall be a member of International Accreditation Forum (IAF) and signatory to the International Accreditation Forum Multilateral Recognition Arrangements for Management System Certification;

- (d) “applicant”-means an agency who undertakes food safety audit and for that makes an application in form ‘A’ of the schedule appended to these regulations;
 - (e) “audit report” in relation to the food safety audit criteria means a written record of the observations, findings and conclusion of the audit;
 - (f) “ auditing agency” means an auditing agency recognised by the Food Authority for undertaking food safety audit specified in these regulations;
 - (g) “Food safety audit” means a systematic and functionally independent examination of food safety measures adopted by the manufacturing units to determine such measures and related results that meets with objective of food safety and the claims made in their behalf;
 - (h) “risk” in relation to any article of food, means the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard;
 - (i) “third party” means an organisation or agency other than the Food Authority and food business operators.
- (2) Words and expressions used herein and not defined in these regulations but defined in the Act, shall have the same meaning as assigned to them in the Act.

Part-II
RECOGNITION OF AUDITING ORGANISATION or AGENCY

3. Recognition of auditing organisation/agency.-(1) The auditing agency shall be registered in India.
- (2) The auditing agency shall hold a valid accreditation ISO/IEC 17020 and ISO/IEC 17021 for the required food categories specified by the Food Authority.
- (3) The auditing agency shall have a minimum of three auditors with the qualifications and shall meet the following minimum requirements, namely:-
- (i) Bachelor’s degree in Food or Dairy Fisheries or Oil Technology or Biotechnology or Agricultural or Veterinary Sciences or Bio-chemistry or Microbiology or Chemistry from a recognised university;
 - (ii) should have successfully completed Accredited Lead Auditor course in Food Safety Management System recognised by International Register of Certificated Auditors (IRCA) and/or any other body specified by the Food Authority from time to time;
 - (iii) knowledge of the Act and the rules and regulations made there under;

- (iv) sector specific knowledge of hygienic and sanitary practices, processing techniques, hazards identification, analysis and control and knowledge of contaminants, allergens, etc;
- (v) any other additional requirement or mandatory training as maybe specified by the Food Authority.

(4) Criteria for recognition may be relaxed by the Food Authority for the reasons to be recorded in writing.

4. Procedure for recognition.- (1) The auditing agency shall make an application in Form A and enclose documents as per annexure of the schedule appended to these regulations along with fees as specified by the Food Authority.

(2) The Food Authority shall scrutinise all applications for recognition and on scrutiny, deficiency, if any, shall be informed to applicant within thirty days from the date of receipt of applications, who in turn shall provide the information sought by the Food Authority within fifteen days of the receipt of the communication, failing which the application shall be rejected without any further reference. The fees paid by the applicant shall not be refunded in that case.

(3) The Food Authority shall constitute a Screening Committee for recognition of the auditing agency from time to time.

(4) If the Food Authority is satisfied that the applicant fulfills all the requirements as specified in these regulations the application shall be placed before the Screening Committee for making recommendations to the Food Authority for its recognition.

5. Terms and conditions of recognition.- (1) On the recommendation of the Screening Committee, the Food Authority may recognise the auditing agency.

(2) The auditing agency shall be provided with a certificate of recognition in Form 'B' of the schedule with a unique identification number.

(3) The certificate of recognition granted under these regulations shall be valid for a period of three years.

(4) The recognition that has been granted to the auditing agency shall be liable to be suspended or cancelled by the Food Authority

6. Procedure for renewal.- (1) The auditing agency may make an application for renewal of recognition not later than sixty days prior to the date of expiry specified in the certificate of recognition.

(2) The Food Authority shall consider the application for renewal on the basis that it continues to meet the criteria for recognition specified in the regulations and based on the performance of the auditing agency over the period of three years, and place the same before the Screening Committee for evaluation.

(3) On the recommendation of the Screening Committee, the Food Authority shall renew the certificate of recognition.

7. Procedure for cancellation or suspension.- (1) The Food Authority may, issue a show cause notice to suspend or cancel the recognition of the auditing agency by an order on the following grounds, namely,-

(i) the auditing agency has made an application to be declared an insolvent;

(ii) the auditing agency has failed to carry out any orders issued by the Food Authority;

(iii) the auditing agency has committed a fraudulent act;

(iv) the auditing agency has in any other manner become incompetent to continue to be accredited food safety auditor as required under these regulations;

(v) the auditing agency has failed to provide access to their records and furnish necessary information to the Food Authority to conduct the assessment or investigation;

(vi) the auditing agency has failed to take timely and necessary corrective measures, if any, as directed by the Food Authority;

(vii) the finding of the Screening Committee on receipt of complaints and conduct of the auditing agency;

(viii) the auditing agency has provided false information with regard to conflict of interest;

(ix) any other reason that the Food Authority may specify in this behalf.

(2) The auditing agency shall file reply with the Food Authority within fifteen days from the date of receipt of the show cause notice, failing which the decision to cancel or suspend shall be taken by the Food Authority.

(3) The Food Authority shall consider the reply filed by the auditing agency and pass such orders as deem fit under the provision of these regulations within thirty days of the receipt of the reply of the auditing agency.

(4) The Food Authority may revoke the suspension of recognition upon consideration of the corrective measures taken by the auditing agency under these regulations.

(5) In case of cancellation, the applicant shall make a fresh application for recognition to the Food Authority after a period of six months from the date of such cancellation.

(6) The recognition of the auditing agency shall be deemed to be suspended or cancelled, if its accreditation is suspended or cancelled by its accrediting body.

- (7) The auditing agency aggrieved by the order of suspension or cancellation of recognition, may file an appeal to the Chairperson of the Food Authority.

Part-III

AUDITING PROCEDURE

8. Audit process.- (1) The Food Authority shall, from time to time specify the category or type of food businesses which shall be subject to mandatory food safety auditing, primarily based on their risk classification. The classification of food business shall be done after consideration of the major risk factors like food type, intended customer use, nature of activity of the business, volume of the business, method of processing and/or any other factors that the Food Authority may specify in this behalf. Such food businesses shall get their business audited by the recognized auditing agency as per the frequency specified by the Food Authority.

(2) Food businesses which are not mandatorily subject to food safety auditing but are desirous of getting audited by the recognized auditing agency, can opt for the same.

(3) Food businesses in which food safety audits have been satisfactorily conducted may be subject to less frequent inspections by the Central or the State licensing authorities except for regulatory purpose:

Provided that in case of any complaints against the food businesses or when it comes to the knowledge of the Food Authority that the public health and safety is at risk, the Food Authority shall have the discretion to undertake more frequent inspections.

(4) The audit process involved for assessing the food safety management system of a Food Business Operator shall be based on IS/ISO 19011:2011 (Guidelines for auditing management systems).

9. Audit examination.- (1) Audit examination shall cover collection of objective evidence and documenting audit observations. Evidence can be collected through interviews, examination of documentation and observation of activities.

(2) Where the deficiencies or non-conformances detected, they shall be documented clearly and concisely and shall point out the regulatory requirements that are being contravened.

(3) During the audit process, the auditing agency shall verify the compliance not only with the food safety measures but also with the Food Safety Standards

Regulations as applicable other than those which may require specific sampling and laboratory analysis of the products.

- (4) The auditing agency shall check relevant documents related to laboratory reports maintained by the Food Business Operator as part of compliance with various regulations made under the Act.

10. Duties of auditors.-The auditor shall perform the following duties, namely,-

- (i) conduct food safety audit of Food Business Operator ;
- (ii) check compliance with the provisions of the various regulations made under the Act;
- (iii) conduct pre-commissioning inspection of newly established food business units, as directed by the Food Authority;
- (iv) keep all commercial-in-confidence material confidential, which includes process and product formulation information, food safety program information and audit outcomes;
- (v) forward the audit report to the Food Authority within fifteen days of the conduct of food safety audit;
- (vi) carry out necessary follow-up action, including further audits, to check whether any corrective action was taken to remove any deficiency of such food safety program identified in an audit;
- (vii) maintain the confidentiality during food safety audit;
- (viii) any other related assignment which the Food Authority may specify from time to time.

11. Audit report.- (1) The auditor shall report the findings of the audit to the food business after the completion of the audit, wherein the food business shall be given an opportunity to discuss the findings and provide further information or clarification to the auditor, if necessary.

(2) The auditing agency shall submit the audit report in the format specified by Food Authority to the Food Business Operator immediately after completion

of the audit and also to the Central or State Licensing authority within fifteen days. The audit report shall clearly bring out the finding or non conformities.

(3) The non-conformities of the audit may be classified into two categories,namely,-

(I) Major non-conformity- When there is a serious failure in the food safety management system of the Food Business Operator, which may result in adverse health consequence possibly even fatal, the auditor shall report such findings to the Central or State Licensing Authority within twenty four hrs. The Central or State Licensing Authority after ascertaining the seriousness of the situation shall take regulatory action against the concerned food business operator.

(II) Minor non-conformity- When there is a shortcoming in the food safety management system or regulatory contravention of the Food Business Operator , which may not cause any adverse health consequence, the auditor shall setup an appropriate timeframe for its rectification and follow up, so that the non-conformance could be rectified.

(4) Failure by food business operator to rectify theminor non conformity within the specified timeframe shall be referred to the Central or State Licensing Authorities, as the case may be.

(5) The auditor may recommend in writing the reasons for the change in audit frequency of the food business operator to the Central or State Licensing Authority based on the audit.

12. Conflict of interest. -(1) Theauditing agency shall give a declarationin Form 'C' of the schedule before accepting food safety audit of a Food Business Operator.

(2) The recognition of any auditing agency shall be suspended or cancelled immediately by the Food Authority on the event of providing false information on conflict of interest.

Part-IV
AUDIT MONITORING SYSTEM

13. Audit monitoring .-The Food Authority shall monitor the performance of the recognized auditing agency in the following manner, namely:-

(i) The monitoring mechanism shall include review of the audit reports and performance; on site assessment of the auditors to ensure their competency of auditing the food safety management systems and the regulatory requirements; assessment of auditing agency on the basis of report of the accreditation body and any other mechanism as specified by the Food Authority.

(2) Handling disputes.- (i) The Central or the State Licensing Authorities shall be the contact point for Food Business Operator to engage in case of any dispute or disagreement with auditors.

(ii) In case of any non-cooperation or resistance to the working of the auditing agencies or auditors by food business operator, the same shall be referred to the Central or the State Licensing authorities for resolution.

(3) Record keeping.- (i) The final conformance report and all other documents related to the audit conducted including the first audit report, actions taken and successive communications on rectification measures shall be preserved by the auditing agencies at least for a period of five years and full confidentiality of the documents shall be maintained.

(ii) Food Business Operator shall maintain all records of audit findings and rectification for a period of five years.

Schedule

Form A

(See sub-regulation (i) of regulation 4)

Application Form for Recognition/Renewal of Recognition of Auditing Agency

Photo (Authorised signatory in case of auditing agency)

1) Name of auditing agency:	
2) Name of contact person:	
3) Address(with Pin Code):	
4) Contact Details: a) Tel No.(with STD code) b) E-mail of the contact person/Website address of the Organization (if any)	
5) Legal Entity Status (attach documentary evidence):	
6) Detail of accreditation certificate (attach copy):	Certificate No:
	Validity up to:

7) Specialized areas of work:					
8) Detail of auditors enrolled (attach copy):					
9) Educational qualification of auditor					
10) Training details of auditor (copy of certificate)	S. No	Title of course	Conducted/Or ganized by (Name and Address)	Dates	
				From	To
11) Inspection/auditing record details for past two year (food category wise)					
12) Any other information regarding food safety audit competency					
13) Recognition number : (in case of renewal)					

I _____ (authorised signatory) _____ S/o,
D/o _____ R/o _____ do
hereby solemnly affirm and declare that all information and particulars furnished here by me are true and correct to the best of my knowledge. I further declare that the food safety auditing to be conducted by me or through my auditor shall conform to the requirements of the Food Safety and Standards (Food Safety Auditing) Regulations, 2017.

Signature of authorised signatory with stamp

List of documents to be enclosed with the application:

- a) Application fee receipt/DD or pay order
- b) Certificate of accreditation
- c) Educational qualification certificate of all auditors.
- d) Lead auditor course certificate.
- e) Confidentiality agreement
- f) A copy of the last assessment report by the accreditation body
- g) Details of industry auditing experience of all auditors.



Recognition Number.....

Certificate of Recognition

(See regulation 5)

this is to certify that.....(name of auditing agency) has been recognised by the Food Safety and Standards Authority of India for the purpose of auditing of food business operators licensed under Food Safety and Standards Act, 2006 and subject to the Food Safety and Standards (Food Safety Auditing) Regulations, 2017.

Name and address of auditing agency	Issued on/ renewed on	Valid upto	Scope

Note: This certificate must not be altered in any way. Intentional misuse of this certificate will result in cancellation without prior intimation.

Signature of Director with stamp

Declaration

(See sub-regulation (i) of regulation 12)

I _____ S/o, D/o _____ state that the food safety audit of M/s _____ having license number _____ has been audited by my auditing agency. In this context, I hereby declare that:

- a) my auditing agency or its personnel/auditor have not provided any training, guidance, Food Safety Certification or consultancy to and not carried out internal audits of the above said food business operator or any of its parent or subsidiary for last two years.
- b) my auditing agency or its personnel/auditor does not own or have financial interest in, manage or otherwise control to the above said food business operators or any of its affiliate, parent or subsidiary.
- c) my auditing agency or its personnel/auditor have not been employed by the above said food business operator for last two years.
- d) my auditing agency has not carried out the food safety audit of the above said food business operator for more than three consecutive audit.

Signature of authorised signatory /Auditor with stamp

[F.No. TPA/01/REG/FSSAI-2017]

(Pawan Agarwal)

Chief Executive Officer